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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/444,144	11/20/99	HOWELL	M CYT0001

MARK D HOWELL PH.D.
2401 RESEARCH BOULEVARD
SUITE 205
FORT COLLINS CO 80526

HM22/1220

EXAMINER

HELMS, L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED:

12/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/444,144

Applicant(s)

Howel et al

Examiner

Larry R. Helms Ph.D.

Group Art Unit

1642



☒ Responsive to communication(s) filed on 6 Nov 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- ☒ Claim(s) 1-34, 37, 38, 40-42, and 50-56 is/are pending in the application.
- Of the above, claim(s) 4, 6-9, and 28-33 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-3, 5, 10-27, 34, 37, 38, 40-42, and 50-56 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. Claims 35, 36, 39, and 43-49 have been canceled.
Claims 50-56 have been added.
Claims 1, 10-14, 18, 20, 22, 25-27, 34, 40, 41, and 42 have been amended.
Claims 1-34, 37-38, 40-42, and 50-56 are pending.
2. Claims 4, 6-9, 28-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction (election) requirement in Paper No. 6.
3. This application contains claims drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
4. Claims 1-3, 5, 10-27, 34, 37-38, 40-42, and 50-56 are under examination and will be examined to the extent they read on the species elected in paper # 6 as: inert medium of a macroporous bead, inhibitor of soluble receptors for tumor necrosis factor alpha, and binding partner is an antibody.
5. The text of those sections of Title 35, U.S.C. Code not included in this Office Action can be found in a prior Office Action.
6. The following Office Action contains some NEW GROUNDS of rejections.

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Claim Objections

7. Claims 10-11 and 41 are objected to because of the following informalities:
- a. Claims 10 and 11 include species drawn to non-elected inventions.
 - b. Claim 41 is amended improperly. The claim does not contain brackets around the term “or” and does not contain an underline for the “/” inserted into the claim. Applicants attention is drawn to Method of Making amendments See MPEP 1.121.
- Appropriate correction is required.

Rejections Withdrawn

8. The rejection of claims 1-3, 5, 10-27, 34-43 under 35 U.S.C. 112, second paragraph, as indicated in the previous Office Action under 7a-b, and d-g, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.
9. The rejection of claims 14-15, 18-23, and 25-27 under 35 U.S.C. 112, first paragraph is withdrawn in view of the amendments to the claims.

Response to Arguments

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10. The rejection of claim 11 under 35 U.S.C. 112, second paragraph, as indicated in the previous Office Action under 7c, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

The response filed 11/6/00 has been carefully considered but is deemed not to be persuasive. The response states that "As set forth in the specification on page 6, lines 7-22, infectious microorganisms are known in the art to produce molecules that are homologues of mammalian immune system inhibitors." This is not persuasive because it is still not clear what homology is needed to encompass a "homologue" described in the claims. Does the "homologue" have the same structural and functional characteristics of the molecule it is to be homologous with?

11. The rejection of claims 1-3, 5, 10-27, 34, 37-38, 40-42, and newly added claims 50-56 under 35 U.S.C. 103(a) as being unpatentable over Lentz (U.S. Patent 4,708,713, issued 11/24/87, IDS #4) and further in view of Selinsky et al (Immunology 94:88-93, 5/1998, IDS #4) and Maraskovsky et al (U.S. Patent 6,017,527, filed 12/12/96) is maintained.

The response filed 11/6/00 has been carefully considered but is deemed not to be persuasive. The response states that "Lentz can be viewed as a teaching away from a method which separates blood into cellular and acellular component" as evidenced by column 10, lines 204) (see page 13, 2nd paragraph of response). In response to this argument the cited passage of Lentz states "although not as efficient as the preferred embodiment, the blood from the patient

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can be first treated to separate plasma therefrom by suitable means” (see column 10, lines 2-4). Thus, Lentz does teach separation of blood into plasma component which is a acellular and cellular separation. The response further states “Selinsky et al do not teach or suggest an ex vivo method for contacting an acellular portion of a bodily fluid” (see page 14). In response to this and other arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The Selinsky et al reference teaches that the soluble tumor necrosis factor receptor type I is removed by Ultraphoresis (see page 88) and thus with the knowledge of Lentz one would know that soluble immune system inhibitors can be removed from the acellular component of blood. In addition, Selinsky et al state that removal of naturally occurring plasma inhibitors of an inflammatory response provides significant clinical benefits to patients (see introduction). The response continues in stating “Marakovsky et al provide an exogenous source of immune stimulator to a patient, whereas the present method removes an inhibitor” (see page 14 of response). In response to this argument, Marakovsky et al is cited for providing a teaching of immobilized antibody onto surfaces such as beads and the antibody removes cells that contain a specific antigen. The response continues to state “it appears that in the present case the only suggestion for the Examiner’s combination of teachings in the cited references improperly stems from Applicant’s own disclosure and not from the cited references themselves.” (See page 17, first full paragraph). In response to applicant's argument that the

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examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Thus, it would have been obvious to use the method of Maraskovsky et al to immobilize an antibody of Selinsky which specifically binds to sTNFRI, wherein the sTNFRI inhibits the immune response, and is removed in the method of Lentz.

The following is a NEW GROUND of rejection.

Claim Rejections - 35 USC § 112

12. Claims 10 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 10 recites the limitation "immune system inhibitor" in claim 1. There is insufficient antecedent basis for this limitation in claim 1.

b. Claims 12-13 are indefinite for reciting "naturally binds" in claim 12 because the exact meaning of the phrase is not clear. Does the phrase mean a binding partner that is the binding

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partner naturally in the cell. For example, does the phrase mean only a receptor or a protein that is found naturally in the cell or does the phrase mean any binding partner that would “naturally” bind to the inhibitor?

Conclusions

13. No Claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879


SHEELA HUFF
PRIMARY EXAMINER